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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,158	08/01/2005	Stanley George Bonney	P33086	5397

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
08/19/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/519,158	BONNEY ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32 and 34-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32 and 34-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/21/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 12/21/04. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27, 36 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 27, 36 and 40 contains the trademark/trade name Eudragit E100, 4135F or L100. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe enteric and controlled release polymers and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 30, 34, and 37-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Omura (USPN 6,303,144 hereafter '144). The claims are drawn to a pharmaceutical dosage form comprising a cavity, a drug filled into the cavity and a film covering said cavity.

The '144 patent teaches a dosage form comprising a cavity comprising a drug composition and a film covering said cavity (abstract, Figure 1). Part **1A** forms a mouth surrounding the drug dosage **3A**. Film portion **2A** covers the drug portion and cavity of part **1A** (Figure 1 col. 6, lin. 65-col. 7, lin. 22). The dosage from is released in the gastrointestinal tract (col. 7, lin. 45-55). The film comprises immediate release polymers such as hydroxypropylcellulose (col. 8, lin. 20-22). The body forming the cavity comprises delayed release polymers such as Eudragit blend polymers (col. 4, lin. 65-col. 5, lin. 10). These disclosures render the claims anticipated.

Claims 1, 2, 5-25, 28-32, 34, 35, 37-39 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Wong et al (USPN 5,417,682 hereafter '682).

The '682 patent discloses a multi-component pharmaceutical dosage form comprising a first and second cavity (Figure 8, part 30a and 30b). The capsule comprises adjacent walls that extend from the base wall (parts 24a) and define the first and second mouth (Figure 8). This skirt wall is a common to both cavities. The cavities are separated by a wall (part 17) that retains the

drug components and keeps them separate (parts 30a and 30b). The capsule further comprises a second film (part 16b). The first cavities fit into the second film (part 16b) as a plug and socket relation ship (Figure 8). The formulation comprises immediate release gelling polymers such as polyvinyl alcohol, pgla polymers and hydroxypropylmethylcellulose (col. 12, lin. 65-68 and col. 17, lin. 1-15). The capsule further comprises an enteric, pH dependent polymer coatings (Example 3, col. 16, lin. 30-35). The capsules are formed by forming the walls, filling the cavities with the drug components (parts 30 a and 30b), and closing the multi-components (Figure 12 a and 12b, col. 15-52-68, example 9). The capsule shell has a thickness of 8-9 mils (approximately 200-225 microns) (example 3). Theses disclosures render the claims anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 4, 15, 16 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Wong et al (USPN 5,417,682 hereafter '682) in view of Pace (USPN 4,281,763 hereafter '763).

As discussed above the '682 patent discloses a multi-compartment capsule dosage form comprising two cavities comprising multiple coating, films and walls defining the cavities. The capsules multiple parts are sealed tightly together (example 9). However the reference is silent to a specific sealing technique. Ultrasonic welding is well known in the art especially with two part drug capsules. This can be seen in the '763 patent.

The '763 patent discloses a capsule comprising a cavity that is defined by capsule wall (Figure 1). The capsule halves are joined together as a plug and socket and sealed via an ultrasonic weld (Figures 4 and 5, col. 2, lin. 28-40). It would have been obvious to apply the seal of the '763 patent to the capsule preparation of the '682 patent in order to quickly and tightly seal the capsule components.

It would have been obvious to one of ordinary skill in the art under the suggestions of the '682 patent to tightly seal the capsule to use the ultrasonic sealing technique of the '763 patent in order to provide a fast and effective 360 degree seal. One of ordinary skill in the art would have been motivated to combine the prior art as such with an expected result of a stable capsule useful for oral administration.

Claims 1, 15, 16, 22, 27, 34 and 36 rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Wong et al (5,417,682 hereafter '682) in view of Akiyama et al (USPN 5,948,773 hereafter '773).

As discussed above the '682 patent discloses a capsule preparation comprising a mixture of immediate release and controlled release polymers. The reference is however silent to the specific combination of the instant claims. This combination of Eudragit polymers can be found in the prior art as seen in the '773 patent.

The '773 patent discloses a capsule formulation comprising drug matrix comprising a mixture of polymers (col. 13, lin. 28-45, col. 16, lin. 40-45). The polymers include Eudragit E100 and L100 9col. 14, lin. 60-68). These polymers can be used in combination (col. 15, lin. 5-8). It would have been obvious to include these polymers into the formulation of the '682 patent in order to improve the stability and release properties of the formulation.

One of ordinary skill in the art would have been motivated to combine the enteric polymers of the '773 patent under the suggestion of the '682 patent into this formulation in order to improve the release properties ensuring a stable release of the active agents. One of ordinary skill in the art would have been motivated to combine the prior art as such with an expected result of a stable controlled release capsule formulation.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 7:00-4:30; every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618